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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,325	09/02/2004	Kenji Tayama	1254-0255PUS1	8827

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/506,325	TAYAMA ET AL.	
	Examiner	Art Unit	
	Timothy P. Thomas	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims

Acknowledgement is made of applicant's preliminary amendments to the claims, filed on 09/02/2004. Claims 3, 4 have been amended. New claims 5-13 have been added. Claims 1-13 have been examined on the basis of the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hypertension or lowering high blood pressure, does not reasonably provide enablement for preventing hypertension. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

a) Breadth of the claims. The claims include broad wording that would give applicant the legal boundaries for preventing hypertension in every population group, from any possible cause or associated disease state, without regard for diet (apart from ingestion of acetic acid), general state of health, level of physical activity, level of stress, age of individual, disease condition, etc.

b) Nature of the invention. The invention involves a composition for preventing hypertension and a method of preventing, ameliorating or treating hypertension, comprised of long term oral ingestion of acetic acid containing food or composition

c) State of the prior art. The art in the field of hypertension includes known methods of treating and reducing high blood pressure and hypertension. Some causes and risk factors are known, other long term beliefs have changed (i.e. sodium, once thought to be responsible for hypertension has now been only weekly correlated to hypertension). Some of the many causes of hypertension are unknown. However, no prevention methods, aside from lifestyle changes, have been demonstrated.

d) Level of one of ordinary skill. The level of skill in the art is high.

e) Level of predictability in the art. The art in the field of prevention of high blood pressure is somewhat unpredictable. For instance, sodium once thought to be causative of hypertension, has been recently reported to only have a week correlation to increased blood pressure and the reduction of sodium intake has only minimally lowered blood pressure in the general population, although certain individuals are very sensitive to sodium intake; they have large blood pressure changes in response to

modification of salt intake (Franco, et al.; J. Am. Coll. Nutr. 2006 Jun; 25 (3 Suppl.): 247S Abstract).

f) Amount of guidance presented by applicant. Applicant presents guidance for preparing and ingesting acetic acid containing compositions, and demonstrates the resultant lowering of blood pressure. It is projected that this lowering of high blood pressure will also prevent the development of hypertension. However, applicant has not demonstrated such prevention in any population group, or long term blood pressure reduction longer than a couple of months. Nor has applicant described a mechanism by which reduction in blood pressure might occur in every population group, let alone the prevention of hypertension. Hypertension is caused by many different health conditions, including nutrition, weight (Paillard; Presse Med.; 2006 Jun; 35 (6 Pt 2) : 1077-80 Abstract), various diseases, such as diabetes (Erdine, et al.; Herz. 2006 Jun; 31 (4):331-8; Abstract) and age (Nash; Geriatrics, 2006 Dec; 61 (12):22-8; Abstract). Applicant has addressed none of these factors (with the possible exception of one nutritional component).

g) Number of working examples. Applicant presents studies demonstrating reduction in blood pressure over 15 weeks in patients with mild to moderate hypertension, but excluded patients with more serious health conditions. No examples of prevention have been presented.

Given the analysis of the above factors which the Courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have needed to have practiced undue and excessive

experimentation, with little guidance from applicants, in order to develop or use compositions or methods of treatment that would prevent hypertension.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-6, 9-10, 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kondo, et al. (Biosci. Biotechnol. Biochem., 2001, 65 (12), 2690-4). Kondo teaches long term (8 weeks) ingestion of vinegar and acetic acid compositions and the antihypertensive effects when these compositions are fed to rats (title, abstract, Figure 1).

5. Claims 1-3, 5-8, 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Jones (www.folkmed.ucla.edu). The American folklore is filled with references to the medicinal properties of Vinegar, including instructions for preparing compositions and methods of using to lower blood pressure. Jones has compiled and published the UCLA Folklore Archives, a series of accounts that include references for reducing high blood pressure/hypertension by the ingestion of vinegar or compositions containing vinegar. Vinegar contains 4-8% acetic acid, typically 5% (en.wikipedia.org/wiki/Vinegar; Accessed 3/19/2007); with a density of 0.96 g/mL that corresponds to about 4-8 g, or typically 5 g acetic acid per 1000 g vinegar. Record # 3_5290 records a method to cure

high blood pressure; drinking ½ cup (118 mL) vinegar each a.m., which would correspond to about 5 g acetic acid /1000g vinegar (in the range 0.36 - 30 g/1000g, required by Claims 2, 7, 11). Record # 7_5290 records a method/composition to reduce high blood pressure: take 10 cloves of garlic, cut up finely, add 1 tablespoon of vinegar and eat. 1 tablespoon vinegar corresponds to about 0.75 g dose acetic acid (within the range 0.5 g to 5 g /day, required by claims 3, 7, 12). Record # 5_6369 indicates drinking vinegar and honey everyday, in order to promote health. All of these records indicate ingestion of the vinegar or vinegar containing compositions as the method of treatment; implicit is that the ingestion is long term.

6. Claims 1-3, 5-8, 10-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bragg, Paul C., et al. (1998, Bragg Apple Cider Vinegar: Miracle Health System). Bragg teaches a method to reduce high blood pressure in a patient to near normal in 48 hours, by oral ingestion of an apple cider vinegar (ACV) cocktail (composition containing acetic acid) 5 times daily, which is followed by the Bragg Healthy Lifestyle (a program containing physical, mental, emotional, social and spiritual components, p. 99) and ACV program. The daily ACV cocktail is prepared using 1-2 teaspoons (5-10 mL) ACV, optional honey or maple syrup in a glass of water (about 237 mL), to be taken 3 times per day (p. 96, 2nd paragraph). This corresponds to daily ingestion of about 0.75-1.5 g acetic acid (between 0.5 g to 5 g per day), the acetic acid concentration of the composition taught by Bragg corresponds to 1.05-2.1g acetic acid / 1000g of composition (between 0.36 g to 30 g per 1000 g composition). Although Bragg does not teach a specific consecutive number of days of use, Bragg teaches all

the Bragg children have used ACV since birth for five generations (p. 39; long term oral ingestion).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4, 9, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bragg et al. Bragg teaches all of the components of Claims 1, 5, 10 (on which the instant claims depend), as discussed above. There are only minor differences between the teaching of Bragg and Claims 4, 9, 13. These claims specifically require a period of ingestion of 3 weeks or longer. Bragg does not specifically teach a number of days (beyond the first few days) of using ACV, however, as pointed out above, Bragg does teach its long-term consistent use, since birth, for five generations (as a permanent lifestyle, p. 39). Therefore, to lower high blood pressure and/or reduce hypertension, it

would be obvious to one of skill in the art to use the claimed composition and method every day for a minimum of 3 weeks. The motivation to do so is given by Bragg: if one wants to normalize blood pressure (p. 38), promote a super healthy lifestyle (p. 39), reduce arthritis (p. 40), relieve muscle cramps (p. 40), etc. one will orally consume apple cider vinegar for an extended period of time, at least 3 weeks.

Conclusion

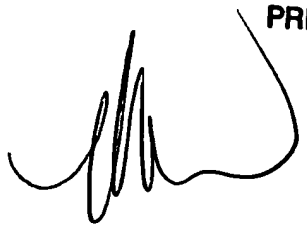
10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (703) 272-8994. The examiner can normally be reached on Monday-Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang, can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy P. Thomas



VICKIE KIM
PRIMARY EXAMINER